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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,485	05/25/2001	Scott D. Feighner	20251P	8604

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,485	FEIGHNER ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7 and 8* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 5/19/04 has been entered. Applicant has amended claims 1-4 and 8. Claims 5 and 6 are cancelled. Claim 7 is withdrawn for being drawn to non-elected subject matter. Claims 1-4 and 8, drawn to the elected invention of Group I are under examination.

2. The rejection of claims 1-6 under 35 U.S.C. 102 is maintained.

Applicants argue the McKee reference (Genomics, 46:426-434, 1997) discloses a "virtual" G protein coupled receptor (GPCR) sequence, which did not actually exist in physical form and was predicted solely on the basis of genomic DNA sequence. Applicants provide no traversal to the Examiners Office Action pertaining to McKee disclosing that the GPR38 receptor is characterized by a 100% query match to SEQ ID NOS: 3 and 5 of the instant application. Applicant further argues that the cited reference described a single protein of unknown function, and fails to provide a coding sequence for the orphan receptor that is disclosed in the publication. Applicants' arguments have been fully considered but are not found persuasive. Examiner agrees McKee does not disclose the specific function of the GPR38. McKee does disclose the receptor is a GPCR and has 35% homology to neurotensin receptor-1 (NT-R1). Although, McKee does not provide a coding sequence for the orphan receptor, McKee does provide the amino acid sequence of claimed receptor (Fig. 1). The claims are drawn to a specific GPCR polypeptide whose specific sequence is disclosed by

McKee. Claims 1-4 are drawn to a product, a protein. It is irrelevant if the nucleic acid sequence is disclosed or not. The genomic clone of GPR38, disclosed on page 427 by McKee, inherently encodes the sequence of the claimed protein, which is disclosed.

Applicants further argue the claimed receptors are claimed by reference to two distinct amino acid sequences, which are encoded by the nucleotide sequences provided in SEQ ID NOS: 2 and 4. Applicants assert that due to the degeneracy of the nucleotide sequence, the prior disclosure of an amino acid sequence does not anticipate the genus of nucleotide sequences, which it is encoded by. Applicant concludes the cited reference does not deprive the motilin receptors or screening method of the instant invention of its novelty. Applicants' arguments have been fully considered but are not found persuasive. The degeneracy of the genetic code is irrelevant in instant case. The protein is being claimed not the nucleic acid. The degeneracy of the genetic code may change the nucleic acid sequence but not that of its encoded polypeptide. All degenerate sequences of the nucleic encoding the GPR38 will result in the amino acid sequence for said GPCR38 disclosed in Fig.1.

3. The rejection under 35 U.S.C. 102 is recast in view of the amended claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by McKee et. al. (See IDS Genomics, Viol. 46, 426-434, 1997).

McKee discloses GPR38 receptor, which is inherently a motilin receptor, thereby meeting the limitations of claims 1-4, absent evidence to the contrary. McKee discloses GPR38 receptor, which has 100% query match to SEQ ID NOS: 3 and 5 of instant application, thereby meeting the limitation of claims 1-4, absent evidence to the contrary. Further the GPR38 is contained in a full-length genomic clone disclosed on page 427, column 1, second paragraph. Although the nucleic acid sequence encoding the GPR38 is not disclosed, the GPR38 clone inherently has the sequence, which encodes the claimed polypeptide. It is the protein, which is being claimed, and not the polypeptide. Therefore the disclosure of McKee meets the limitations of claims 1-4, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKee et. al. (See IDS McKee et. al., Genomics, Viol. 46, 426-434, 1997). in view of Weinshank et al (US Patent 5,155,218).

McKee discloses GPR38 receptor, which has 100% query match to SEQ ID NOS: 3 and 5 of instant application. Further the GPR38 is contained in a full-length genomic clone, disclosed on page 427, column 1, second paragraph. Although the nucleic acid sequence encoding the GPR38 is not disclosed, the GPR38 clone inherently has the sequence, which encodes the claimed polypeptide. The nucleotide sequence of the GPR38 is most closely related to the neurotensin receptor-I (NT-R1)(35% overall protein identity). McKee states, "The ligand-binding and functional properties of GPR38 and GPR39 remain to be determined (see Abstract). In addition, McKee states, "Further studies are

required to identify the ligand-binding and functional properties of GPR38 and GPR39, as neither radiolabeled MK-0677 or neurotensin bound specifically to GPR38 and GPR39 when ex-pressed in mammalian cells (unpublished results)", see page 433, column 2, first paragraph. McKee does not disclose a specific method for determining whether a ligand is capable of binding to the GPR38 receptor.

Weinshank discloses a method for determining whether a ligand is capable of binding to a specific GPCR comprising:

(a) transfecting test cells with an expression vector encoding a GPCR

(b) exposing the test cells to the ligand;

(c) measuring the amount of binding of the ligand to receptor;

(d) comparing the amount if binding of the ligand to GPCR receptor in the test cells with the amount of binding of the ligand to control cells that have not been transfected with the receptor

(e) concluding that compounds that bind only bind to test cells are specific for GPCR.

See column24, line 31-column 25, line 18; columns 9-10; and 3.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the GPR38 disclosed by McKee, in the methods disclosed by Weinshank to determine which ligands were capable of binding to the newly cloned receptor. Further, the ordinary artisan would have been motivated to use GPR38 in the methods disclosed by Weinshank because, as disclosed by McKee, the ligand-binding and functional

properties of GPR38 remain to be determined. McKee specifically states, "further studies are required to identify the ligand-binding and functional properties" of the GPCR, GPC38. The ordinary artisan would have easily been able to produce the transfected cells required to do the assay because transfection of GPCRs is routine in the art, as is assaying for ligands 9seee art provided). Further, the ordinary artisan would have expected success at completing the assay because others have done the claimed assay. For example, McKee has done the assay, if not exactly the same, it is very similar to that claimed in instant invention. McKee did not disclose all the assay steps, but the steps were inherently done to end up with his results. McKee tested the specific binding of radiolabeled MK-0677 and neurotensin to GPR38 expressed in mammalian cells (unpublished results)", see page 433, column 2, first paragraph.

Therefore based on the state of the art at the time of filing of instant application the ordinary artisan would have a reasonable expectation of success at assaying GPR38 for ligand binding.

5 No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
July 21, 2004

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SUPERVISORY PATENT EXAMINER
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